

Center for Drug Evaluation and Research (CDER)

Public Meeting on CDER Standard Core Sets: Clinical Outcome Assessments and Endpoints Pilot Grant Program
FDA Great Room, Building 31
10903 New Hampshire Avenue, Silver Spring, MD 20993-0002

December 5, 2019

AGENDA

Meeting Website: <https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-cder-standard-core-sets-clinical-outcome-assessments-and-endpoints-grant-program>

Docket No. [FDA-2019-N-5157](#)

- 8:30 a.m. Welcome and Introductory Remarks**
Meena Savani, Office of the Center Director (OCD), CDER, FDA
- 8:35 a.m. Overview of CDER Standard Core Sets: Clinical Outcome Assessments (COAs) and Endpoints Pilot Grant Program**
Robyn Bent, OCD, CDER, FDA
- 8:45 a.m. Clinical Outcome Assessments for Acute Pain Therapeutics in Infants and Young Children (COA-APTIC) Grant Program**
Kanecia Zimmerman, Duke University
- Audience Question and Answer
- 9:15 a.m. Migraine Clinical Outcome Assessment System (MiCOAs) Grant Program**
Richard Lipton, Albert Einstein College of Medicine
- Audience Question and Answer
- 9:45 a.m. Break**
- 10:00 a.m. Northwestern University Clinical Outcome Assessment Team (NUCOAT) Grant Program**
Sara Shaunfield, Northwestern University
- Audience Question and Answer
- 10:30 a.m. Panel Discussion**
- Heather Benz, Office of Biostatistics & Epidemiology, CBER, FDA
 - Katie Golden, Coalition for Headache and Migraine Patients (CHAMP), Director of Patient Relations
 - Laura Lee Johnson, Office of Translational Sciences, CDER, FDA
 - Elektra Papadopoulou, Office of New Drugs, CDER, FDA

- Devin Peipert, Assistant Professor of Medical Social Sciences, Northwestern University
- Michelle Tarver, Office of Strategic Partnerships and Technology Innovation, CDRH, FDA
- R.J. Wirth, President and Managing Partner, Vector Psychometric Group
- Kanecia Zimmerman, Associate Professor of Pediatrics, Duke University

Patient Stakeholder Question and Answer

General Audience Question and Answer

11:45 a.m. Closing Remarks